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IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CASE NO. 2:20-cv-00337-JRG
	)	
DAIICHI SANKYO CO., LTD.,	)	
	)	[redacted]
Defendant, and	)	
	)	
ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LTD.,	)	
	)	
Intervenor-Defendants.	)	

DEFENDANTS' MOTION FOR JUDGMENT OF INVALIDITY BASED ON SEAGEN's POST-TRIAL DISCLAIMER AND FOR DISMISSAL OF INFRINGEMENT CLAIMS AS MOOT

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I. INTRODUCTION

Seagen's at-all-costs attempt to avoid a patentability challenge before the Patent Trial and Appeal Board ("PTAB") has caused Seagen to voluntarily disclaim the purported inventions of the asserted claims, thereby rendering those claims defunct and entitling Defendants to judgment in their favor. On April 7, 2022, the PTAB instituted trial based, in part, on "the strong merits of Petitioner's argument that the claims lack enablement." PGR2021-00030, Paper 17 at 3. In response, Seagen hatched a plan to circumvent the PTAB's decision. On April 20, 2022 (after the jury verdict in this action), Seagen disclaimed all the claims of the '039 patent that had *not* been tried to the jury (Claims 6-8). Based on this disclaimer, Seagen then moved for Adverse Judgment in the PGR (PGR2021-00042) that had been instituted to review only those claims. Because an adverse judgment would dispose of that proceeding entirely, Seagen then argued to the PTAB that it should grant rehearing and de-institute trial in the companion proceeding, PGR2021-00030, where the claims tried to the jury (1-5, 9, and 10) were challenged. Seagen argued that institution should be denied in PGR2021-00030 because of the advanced stage of litigation in this Court on those particular claims and the fact that their disclaimer gambit had eliminated any overlap in issues between the two PGR proceedings.

For the time being, Seagen's stratagem prevailed in the PTAB. The PTAB Panel granted Seagen rehearing in PGR2021-00030 and de-instituted trial, and then on July 25, 2022 entered Adverse Judgment in PGR2021-00042. But Seagen's stratagem was too clever by half. Seagen's disclaimer of Claims 6-8, and the resulting Adverse Judgment and cancellation of those claims, requires judgment in Defendants' favor on Claims 1-5, 9, and 10. Because those asserted claims are not patentably distinct from the claims that Seagen disclaimed, and on which the PTAB entered judgment, Seagen's cause of action on the asserted claims is extinguished. Daiichi Sankyo Japan and Intervenor-Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca UK Ltd.

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(collectively, "Defendants") accordingly file this motion for judgment based on disclaimer and cancellation.

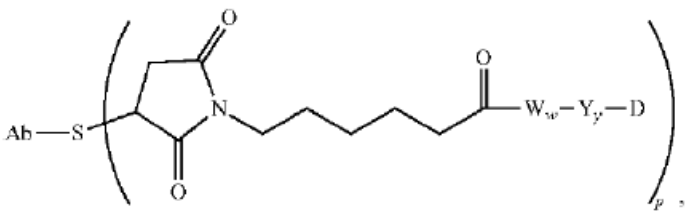
II. STATEMENT OF ISSUES TO BE DECIDED BY THE COURT

Defendants respectfully request that this Court decide the following issues:

- Whether Seagen's disclaimer of Claims 6-8 has surrendered property rights in any other claims that are not patentably distinct.
- Whether the PTAB's Adverse Judgment against Seagen on Claims 6-8 extinguishes Seagen's cause of action for infringement of any other claims that are not patentably distinct.
- Whether asserted Claims 1-5, 9, and 10 are not patentably distinct from Claim 8, thus requiring this Court to enter judgment in favor of Defendants on these claims and declare Seagen's infringement claims moot.
- Whether, independent of patentable distinction, Seagen's disclaimer of Claims 6-8 has disavowed the full scope of asserted Claims 1-5 and 9-10 and invalidated those claims by improper amendment, thus requiring this Court to enter judgment in favor of Defendants on these claims and declare Seagen's infringement claims moot.

III. THE RELEVANT CLAIMS OF THE '039 PATENT

All claims of the '039 patent are directed to types of ADCs. DX-0001 at Claims 1-10. Claim 1 claims "[a]n antibody-drug conjugate having the formula:



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. . . wherein . . . Ab is an antibody . . . Y is a Spacer unit, y is 0, 1, or 2, D is a drug moiety, p ranges from 1 to about 20 . . . [and] wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody drug conjugate or an intracellular metabolite of the antibody-drug conjugate."

All claims of the '039 patent depend from Claim 1, meaning they include all the elements of Claim 1 and add additional limitations. Claim 2 depends from Claim 1 and recites: "wherein Y is a self-immolative spacer." Claim 3 depends from Claim 2 and recites: "wherein y is 1." Claim 4 depends from Claim 3 and recites: "wherein p is about 3 to about 8." Claim 5 depends from Claim 4 and recites: "wherein p is about 8."

Claims 6-9 are dependent claims, each directed to "[t]he antibody-drug conjugate of claim 1, 2, 3, 4, or 5." Each of Claims 6-9 recites a limitation with a "wherein" clause, thus claiming a limited class of Claim 1-5 ADCs. *See Endo Pharm. Inc. v. Teva Pharm. USA, Inc*., 919 F.3d 1347, 1355 (Fed. Cir. 2019) (discussing use of "wherein clause" to limit the claim).

Claims 6 and 7 recite the ADCs of Claims 1-5 wherein bioavailability of the ADC or an intracellular metabolite thereof is improved.

Claim 8 recites "[t]he antibody-drug conjugate compound of claim 1, 2, 3, 4, or 5, *wherein* the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of the antibody-drug conjugate." DX-0001 at Claim 8 (emphasis added). Claim 8 is thus a subclass of the Claim 1-5 ADCs that has the characteristic of intracellular cleavage of the drug moiety from an intracellular metabolite. This language, however, is wholly included as one of only two intracellular cleavage options recited in Claims 1-5. As such, Claim 8 does not disclose or claim anything new, but is simply only a part of what is already expressly recited in Claims 1-5. The person of ordinary skill in the art (POSA) would therefore understand that the scope of narrower

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Claim 8 is fully within the scope of broader Claims 1-5. Exh. A ¶¶ 18-20.

Claim 9 recites the ADCs of Claims 1-5 "wherein the antibody is a monoclonal antibody." Claim 10 depends from Claim 9, claiming "[t]he antibody-drug conjugate of claim 9, wherein the antibody is a humanized monoclonal antibody."

IV. RELEVANT PROCEDURAL HISTORY

Seagen filed this suit for patent infringement (the "Texas Litigation") on October 20, 2020. In December 2020, Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP ("Petitioners") filed a PGR for review of Claims 1-5, 9, and 10 (PGR2021-00030), challenging the patentability of all claims that were then being asserted by Seagen in this present action. In January 2021, after Seagen expanded the Texas Litigation to add counts of infringement for Claims 6-8 of the '039 patent, the Petitioners filed a second petition for PGR (PGR2021-00042). On April 7, 2022, the PTAB instituted both proceedings, thereby putting the patentability of all the claims of the '039 patent into jeopardy in an adversarial setting. Of particular significance, the PTAB expressly acknowledged that Petitioners had presented "strong merits . . . that the claims [challenged in PGR2021-00030, *i.e.*, Claims 1-5, 9, and 10,] lack enablement" and that the "related proceeding PGR2021-00042 [challenging other claims of the '039 patent, *i.e.*, Claims 6-8], . . . *has issues almost identical to* those in [PGR2021-00030]." PGR2021-00030, Paper 17 at 3 (emphasis added).

Meanwhile, in this Court, Seagen chose to proceed to trial only as to Claims 1-5, 9, and 10, having earlier withdrawn its claims that Defendants infringed Claims 6-8 of the '039 patent. Dkt. 121 at 3 n.2. On April 8, 2022, the jury rendered a general verdict that Defendants infringed at least one of the asserted claims, but did not specify which claims were infringed. Dkt. 369. This Court entered judgment on July 19, 2022. Dkt. 432. Post-trial motions have not yet been filed.

Seagen no doubt feared that the PTAB would declare all claims unpatentable, including the claims that the jury had found infringed, after the PTAB instituted post-grant review based on

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its conclusion that Daiichi Sankyo had presented strong evidence of lack of enablement. In response, Seagen concocted a strategy for escaping post-grant review. Seagen—on its own initiative—filed a "Request for Rehearing," asking the PTAB to "reconsider its Rehearing Decision and deny institution" and specifically noted it disclaimed Claims 6-8. PGR2021-00030, Paper 20 at 1, 3-4 (April 21, 2022). A few weeks later, Seagen requested that adverse judgment be entered against it in PGR2021-00042. PGR2021-00042, Paper 24 (May 11, 2022). Five days later after that, Seagen relied on the adverse judgment in an effort to convince the Board to de-institute PGR on the remaining claims. PGR2021-00030, Paper 26 (May 16, 2022). In the Request, Seagen attempted to insulate Claims 1-5 and 9-10 from the effects of the Adverse Judgment it sought in PGR2021-00042, remarking that, as a matter of procedural rights, "Seagen's request for adverse judgment as to Claims 6-8 does not bear on the validity of Claims 1-5 and 9-10, *as a patent owner always has the option to disclaim claims at its discretion. 37 C.F.R. § 42.73*." *Id*. (emphasis added). Other than this strictly procedural ground, no discussion nor support was provided regarding how and why the requested "adverse judgment as to Claims 6-8 does not bear on the validity of Claims 1-5 and 9-10." *Id.*

Relying on Seagen's specific request for the Adverse Judgment, the PTAB, on July 25, 2022, entered the Adverse Judgment against Claims 6-8, terminating PGR2021-00042. Exh. B.

Defendants now move for relief based on disclaimer and Adverse Judgment, which occurred after the jury and bench trial in this case.

V. ARGUMENTS

A. Seagen's Disclaimer of Claim 8 Invalidates All Asserted Claims Because They Are Not Patentably Distinct

Beginning in 1837, Congress granted patentees the power of disclaimer to avoid "the early accepted general rule [that] a patent with an invalid claim was wholly void." *Ensten v.*

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Simon, Ascher & Co., 282 U.S. 445, 452 (1931). Congress provided, as amended, that the patentee could "make disclaimer of such parts of the thing patented as he shall not choose to claim or to hold," 35 U.S.C. § 65 (1946) (Exh. C); the patentee who claimed a greater invention than to which he was entitled could nonetheless sue "for the infringement of any part thereof, which was bona fide his own, if it is a material and substantial part of the thing patented, and definitely distinguishable from the parts claimed without right …." *Id.* § 71. In the Patent Act of 1952, Congress modified the disclaimer statute in two respects: it required that only whole claims be disclaimed, and eliminated the rule that unreasonable delay in filing a disclaimer would invalidate the entire patent. *See Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1096-97 (Fed. Cir. 1987); S. Rep. No. 1979, 82d Cong., 2d Sess., reprinted in 1952 U.S. Code Cong. & Admin. News 2394, 2420–23.[1] The America Invents Act further amended Section 253(a) in 2011 to eliminate the requirement of the 1952 Act that disclaimer be "without deceptive intention." Pub. L. 112–29, § 20(e), Sept. 16, 2011, 125 Stat. 334. Section 253(a) currently provides:

> Whenever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid. A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.

35 U.S.C. § 253(a). Even if "a claim of a patent is invalid, an action may be maintained for the infringement of a claim of the patent which may be valid," but the patentee cannot recover costs absent disclaimer. *Id.* § 288.

[1] *See also* Proposed revision and amendment of the patent laws, preliminary draft with notes, House Committee on The Judiciary, at 47-48 (January 10, 1950).

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Although the case law on Section 253(a) is sparse, Supreme Court jurisprudence illustrates the nature, purpose, and effect of a statutory disclaimer. A statutory disclaimer relinquishes rights in the disclaimed invention. *See Dunbar v. Myers*, 94 U.S. 187, 193-94 (1876) (disclaimer will have the effect in a pending case "to *limit the nature of the invention secured by the patent*, and to diminish the claims of the patent set forth in the specification") (emphasis added). The public is entitled to rely on the patentee's disclaimer. As the Supreme Court held, interpreting former section 65:

> The disclaimer is a representation, as open as the patent itself, *on which the public is entitled to rely*, that the original claim is one which the patentee does not, in the language of the statute, 'choose to claim or to hold by virtue of the patent.' Upon the filing of the disclaimers, the original claims were withdrawn from the protection of the patent laws, and *the public was entitled to manufacture and use the device originally claimed as freely as though it had been abandoned*.

Altoona Publix Theatres v. Am. Tri-Ergon Corp., 294 U.S. 477, 492 (1935) (emphasis added). "[T]he purpose of the disclaimer statute is to enable the patentee to relieve himself from the consequences of making an invalid claim …." *Marconi Wireless T. Co. of Am. v. United States*, 320 U.S. 1, 58 (1943). Indeed, a disclaimer "could not lawfully be anything but a disclaimer of the fact either of original invention or of first invention." *Union Metallic Cartridge Co. v. U.S. Cartridge Co.*, 112 U.S. 624, 644 (1884).

The Supreme Court held in *Maytag Co. v. Hurley Mach. Co.*, 307 U.S. 243 (1939), that a disclaimer of one claim invalidates other claims of the patent that recite the same invention. In *Maytag*, the patentee had 36 apparatus claims for a washing machine and three method claims (1, 38, and 39) for washing fabrics. Three of those 39 total claims (apparatus Claims 23 and 26 and method Claim 38) had been asserted and invalidated in a prior litigation. *Id.* at 244. But in those days—when mutuality was required for collateral estoppel prior to *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971)—the patentee was free to assert the same patent claims

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against a different defendant despite the earlier judgment of invalidity. *Maytag*, 307 U.S. at 245. In doing so, however, the patentee would run the risk that a court could hold that an invalid claim was not timely disclaimed, which would invalidate the entire patent; under a companion statute, no infringement action could be brought on valid claims "if [the patentee] has unreasonably neglected or delayed to enter a disclaimer," 35 U.S.C. § 71 (1946). *See Maytag*, 307 U.S. at 245.

In an attempt to avoid that risk, the *Maytag* patentee disclaimed method Claims 1 and 38, but not 39. It then asserted apparatus Claims 23, 26, and 29 (but not the remaining method Claim 39) against a different defendant in a second action. *Id.*

The Supreme Court held that the patentee's disclaimer of Claim 38 resulted in the invalidation of undisclaimed method Claim 39 because it was not a distinct invention. A patentee that confessed lack of original invention by disclaimer could only maintain rights in other parts of the patent that were definitely distinguishable from the disclaimed claim. *Id.* at 245. The Court held that Claims 38 and 39 "describe but a single method," and "the difference in verbiage describes no difference in operation or result." *Id.* at 246-47. The Supreme Court held that "[if] Claim 39 describes the same method as Claim 38, it follows that failure either to sue on 39 or to disclaim it along with 38 invalidates the patent." *Id.* at 246. Accordingly, by operation of former sections 65 and 71, the Court held that the entire patent (including the otherwise valid apparatus claims) was invalid. *Id.*

The latter part of the Supreme Court's holding (invalidating the entire patent, including distinct apparatus claims, for failing to timely disclaim an invalid claim) is no longer the law. As the Federal Circuit explained, the Patent Act of 1952 modified the provisions of former sections 65 and 71 that required invalidation of the entire patent because of untimely disclaimer of an invalid claim. *See Allen Archery*, 819 F.2d at 1095-97. Under the revised statutes, "[t]he failure

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of a patentee to disclaim an invalid patent claim does not prevent the patentee from enforcing any remaining claims in the same patent *which are otherwise valid*." *Id.* at 1097 (emphasis added). But nothing changed the core principle, recognized in *Maytag*, that disclaimer invalidates other claims that are not patentably distinct inventions. *See Ingersoll Mill. Mach. Co. v. Gen. Motors Corp.*, 110 F.Supp. 12, 37, 40 (N.D. Ill. 1952) (ruling that "[a] patentee who voluntarily makes disclaimer of a claim prior to any adjudication of his patent is free to retain any other claims in his patent *which are definitely distinguishable* from the claim or claims disclaimed," and upholding the asserted claim because it was "*patentably distinguished*" from the disclaimed one) (emphasis added).

The 1952 Act, as amended, eliminated the power of patentees to disclaim parts of claims, and required instead disclaimer of a "complete claim." 35 U.S.C. § 253(a). It thus discarded the language that "his patent shall be valid for all that part which is truly and justly his own," and that "may make disclaimer of such parts of the thing patented as he shall not choose to claim or to hold by virtue of the patent or assignment." 35 U.S.C. § 65 (1946). And Congress repealed former section 71, recited in *Maytag*, that authorized a patent infringement suit "for the infringement of any part thereof, which was bona fide his own, if it is a material and substantial part of the thing patented, and definitely distinguishable from the parts claimed without right," 35 U.S.C. § 71 (1946); *see Allen Archery*, 819 F.2d at 1095-97. But the core principle remains that a disclaimer surrenders a claim without right of an *invention* that the inventor did not possess or that is otherwise invalid: a disclaimer is a "disavowal of the apparent right to exclude others from something improperly included in the words of his grant." *Ensten*, 282 U.S. at 452. Thus, the rule applied in *Maytag* is still the law under section 253: disclaimer invalidates claims that are not patentably distinct because they cover the same invention to which the inventor is not

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entitled. Indeed, the Senate Report to the 1952 Act, in discussing the elimination of the requirement that "an invalid claim must be disclaimed without unreasonable delay in order to save the rest of the patent," commented that under the 1952 Act:

> if one claim of a patent is invalid, the patentee may take it out. He may sue on the remaining claims which have whatever validity they may have on their own merits. That is, one bad claim does not affect the other claims, *unless they are also bad for similar reasons*.

S.Rep. No. 1979, 82d Cong., 2d Sess. (emphasis added), reprinted in 1952 U.S. Code Cong. & Admin.News 2394, 2401–03 (quoted in *Allen Archery*, 819 F.2d at 1097). Seagen was free to disclaim Claim 8, but it thereby surrenders rights to the invention recited therein. That surrender includes any claims that seek to cover patently indistinct subject matter.

This Court has recognized the operation of disclaimer: "A patentee's statutory disclaimer '*relinquishes the rights of the patent owner*' and cancels the claims subject to the disclaimer." *Lemaire Illumination Techs., LLC v. HTC Corp.*, No. 2:18-CV-00021-JRG, 2019 WL 1489065, at *2 (E.D. Tex. Apr. 4, 2019) (quoting *Rembrandt Wireless Techs., LP v. Samsung Elecs. Co.*, 853 F.3d 1370, 1383 (Fed. Cir. 2017)) (emphasis added). "Therefore, by filing a statutory disclaimer, [the patentee] *relinquished any right to exclude others from the subject matter of [the claim]*." *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (emphasis added).

Because disclaimer forfeits the right to exclude others from the recited invention, not just the verbal formulation of the claim, disclaimer invalidates claims that are not patentably distinct. This fundamental principle of disclaimer accords with the rule, under the law of collateral estoppel, that "an administrative decision of unpatentability generally requires the invalidation of related claims that present identical issues of patentability." *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1377 (Fed. Cir. 2018). "[P]recedent does not limit collateral estoppel to patent claims that are identical. . . . If the differences between the unadjudicated patent claims

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and adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies." *Id.* (quoting *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013)). The same principle applies to claim preclusion: "claims which are patentably indistinct are essentially the same," and thus a prior judgment of invalidity of a claim is preclusive of a patentably indistinct claim. *Simple Air, Inc. v. Google LLC*, 884 F.3d 1160, 1167 (Fed. Cir. 2018); *cf. Application of Yale*, 347 F.2d 995, 1000 (CCPA 1965) (disclaimer of interference counts is treated as prior art and can be used to invalidate patentably indistinct inventions). Further, "when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention." *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1214 (Fed. Cir. 2014). The rule is no different when an invention enters the public domain by disclaimer.

Seagen's disclaimer of Claim 8 invalidates all claims of the '039 patent that are patentably indistinct, and extinguishes its cause of action for infringement on those claims. Indeed, it would be absurd if the law was otherwise. As described below, the Adverse Judgment entered against Seagen precludes Seagen from obtaining claims that are not patentably distinct from Claim 8. Permitting Seagen to continue to assert claims having a scope that would be unpatentable if Seagen sought to now obtain such claims in a continuation application, would be completely contrary to the polices underlying disclaimer and collateral estoppel.

As demonstrated below, *infra* at Section V.C, asserted Claims 1-5, 9, and 10 are patentably indistinct from Claim 8. This Court should vacate the final judgment entered on behalf of Seagen, enter judgment for Defendants of invalidity based on disclaimer, and declare Seagen's infringement claims moot.

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B. The Adverse Judgment Entered Against Seagen Claims 6-8 Requires Judgment for Defendants on All Claims That Are Not Patentably Distinct

Seagen did not merely disclaim Claim 8; it relied on its disclaimer to move the PTAB to resolve the PGR on unpatentability of those claims by entering Adverse Judgment. That Adverse Judgment extinguishes Seagen's cause of action for patent infringement, and is an independent basis for entering judgment in favor of Defendants.

At any time during a PTAB proceeding, "a party may request a[n adverse] judgment against itself[.]" 37 C.F.R. § 42.73(b). "A judgment, except in the case of a termination, disposes of all issues that were, or by motion reasonably could have been, raised and decided." *Id.* § 42.73(a). Although here Seagen specifically moved for an Adverse Judgment, even without a specific request "cancellation or disclaimer of a claim such that the party has no remaining claim in the trial" is "construed to be a request for adverse judgment." *Id.* § 42.73(b)(2). An Adverse Judgment entered by the Board in response to such a request is deemed "final, as the judgment terminate[s] the [PTAB] proceeding." *Arthrex, Inc. v. Smith & Nephew, Inc.*, 880 F.3d 1345, 1348 (Fed. Cir. 2018).

A PGR, like an *inter partes* review, is "an in rem proceeding—a proceeding to reevaluate the validity of an issued patent." *Regents of the Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327, 1345 (Fed. Cir. 2019). And like an IPR proceeding, if claims are revoked in a PGR, the proceeding ultimately terminates in cancellation of claims. 35 U.S.C. § 325(b). And PTO regulations extend the effect of that judgment to other claims that are not patentably distinct. Specifically, 37 C.F.R. § 42.73(d)(3)(i) provides that "[a] patent … owner is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent … [a] claim that is not patentably distinct from a finally refused or canceled claim." Under Rule 42.73, Seagen cannot maintain a cause of action for patent infringement on claims that are not

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patentably distinct from Claim 8, because that is "action inconsistent with the adverse judgment" on those claims.

Even apart from Rule 42.73, the PTAB's adverse judgment would have the same effect. As the three panel judges in *Regents of the University of Minnesota* declared, citing *MaxLinear, Inc.* and *Ohio Willow Wood*,

> To the extent the estoppel provisions in 37 C.F.R. § 42.73(d)(3), prevent a patent owner from obtaining a patent on claims that are patentably indistinct from cancelled claims in an IPR proceeding, that result is no different than what is mandated under traditional principles of res judicata and collateral estoppel. *See B & B Hardware, Inc. v. Hargis Indus., Inc.*, U.S., 135 S. Ct. 1293, 191 L.Ed.2d 222 (2015); *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373 (Fed. Cir. 2018); *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333 (Fed. Cir. 2013). In the absence of such a provision, the result would still be the same (i.e., the later claim is unpatentable for the same reasons as the earlier patentably indistinct claim).

926 F.3d at 1345 n.5 (Additional views of Dyk, Wallach, and Hughes). Administrative judgments, including consent judgments, have preclusive effects on judicial proceedings. *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 107 (1991); *Arizona v. California*, 530 U.S. 392, 414 (2000) ("consent judgments ordinarily support claim preclusion but not issue preclusion"). The Adverse Judgment on unpatentability bars Seagen from proceeding in this action on patentably indistinct claims. *SimpleAir, Inc.*, 884 F.3d at 1167.

The Federal Circuit has recognized a particularly strong form of preclusion from administrative judgments that arises from the cancellation authority of the PTO, and extinguishes a patentee's cause of action even if after a district court enters an appealable final judgment (so long as the final judgment is still reviewable by the judicial department). *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330 (Fed. Cir. 2013). "[W]hen a claim is cancelled, the patentee loses any cause of action based on that claim, and any pending

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litigation in which the claims are asserted becomes moot." *Id.* at 1340. Thus, even if the district court enters a final judgment for purposes of appeal,[2] that would not "preclude application of the intervening final judgment" entered by the PTAB in PGR2021-00042. *See id.* at 1341. Indeed, a final PTAB judgment cancelling a claim would be applied even on appeal, so as long as the entire case was not yet concluded. *Id.* at 1342. "The intervening decision invalidating the patents unquestionably applies in the present litigation, because the judgment in this litigation was not final." *Id.* at 1344. A final PTAB judgment binds this Court "because Congress has expressly delegated [PGR] authority to the PTO under a statute requiring the PTO to cancel rejected claims, and cancellation extinguishes the underlying basis for suits based on the patent." *Id*. Cancellation by disclaimer has the same effect of extinguishing the cause of action, as if the disclaimed claims had never existed, and rendering infringement claims moot. *Sanofi-Aventis U.S., LLC v. Dr. Reddy's Labs., Inc.*, 933 F.3d 1367, 1373 (Fed. Cir. 2019) (citing *Fresenius*); *Lemaire*, 2019 WL 1489065 at *2. Because all the asserted claims that are not patentably distinct from Claim 8 are thus extinguished, judgment of invalidity on all claims should be granted to Defendants on the independent ground of cancellation, and Seagen's infringement claims

[2] This Court denominated the judgment a "final judgment," Dkt. 432, and Defendants plan to file post-trial motions within 28 days of that judgment. However, Defendants note that the judgment is not truly final because, separate from its claim for damages through verdict, Seagen has an outstanding claim for a "running royalty" (*i.e.*, equitable relief to order Defendants to pay a running royalty for post-verdict infringement). Doc. 1 at 12, Prayer for Relief ¶ e; Doc. 390 at 2 (Seagen's declaration of intent to file a motion for "an ongoing and enhanced royalty rate and supplemental damages"). "A 'final decision' generally is one which ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." *Catlin v. United States*, 324 U.S. 229, 233 (1945). There is no final and appealable judgment when the court has not decided the question of future damages. *See United States v. Burnett*, 262 F.2d 55, 59 (9th Cir. 1958); *International Controls Corp. v. Vesco*, 535 F.2d 742, 748 (2d Cir. 1976) ("a judgment cannot be considered final as long as it leaves open the question of additional damages").

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should be dismissed as moot.

Additionally, Seagen's disclaimer of Claim 8 prohibits assertion of Claims 1-5 and 9-10 by virtue of collateral estoppel. The Board's decision in a PGR is entitled to preclusive effect. *See, e.g. Papst Licensing GmbH & Co. KG v. Samsung Elecs. Am., Inc.*, 924 F.3d 1243, 1250-51 (Fed. Cir. 2019) (collecting cases regarding IPR proceedings). As the Federal Circuit has explained, "the general rule is that '[w]hen an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.'" *Papst*, 924 F.3d at 1250 (quoting *B & B Hardware, Inc. v. Hargis Indus., Inc.*, 575 U.S. 138, 148 (2015)). Those requirements were met here. The issue of the validity of Claim 8, including their entitlement to Seagen's asserted priority date, was actually litigated and resulted in institution of trial in PGR2021-00042. This determination was necessary to the Adverse Judgment that ultimately issued (*e.g.*, the patent would not have been eligible for PGR had it been entitled to Seagen's priority date), and that judgment should be preclusive here. *See infra* Section V.C (Claims 1-5 and 9-10 are not patentably distinct from Claim 8); *see also* D.I. 365 at 7-23 (explaining bases for invalidity of Claims 1-5 and 9-10 in this proceeding); PGR2021-0042, Paper 18 at 8-10, 19-42 (explaining the PTAB's decision that the '039 Patent was eligible for PGR).

C. The Asserted Claims are Patentably Indistinct from Claim 8

A claim is "patentably indistinct" when "the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity." *MaxLinear, Inc.*, 880 F.3d at 1377. As applied in this context, a patent claim ("Claim B") is deemed "patentably indistinct" from a cancelled claim ("Claim A") if Claim B would have been

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either anticipated or obvious in light of Claim A, had it been filed at a later time than Claim A. *See*, *e.g.*, *Eli Lilly and Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001) ("A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.").

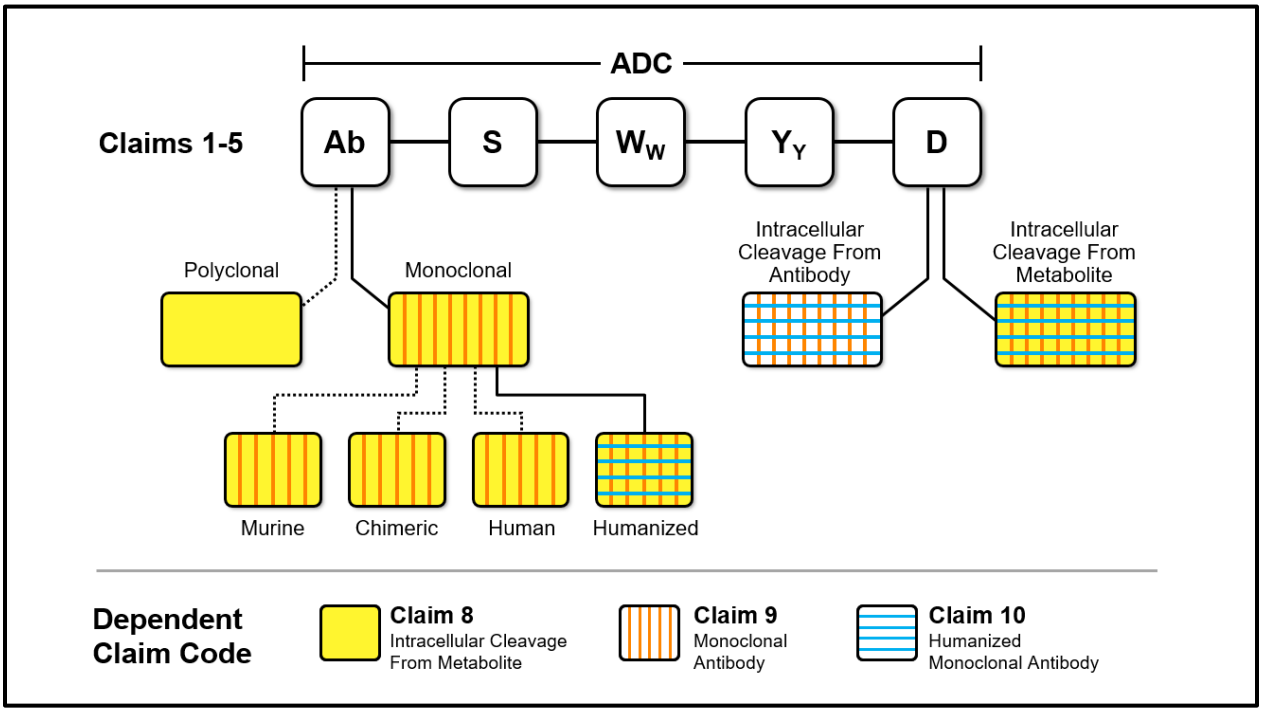
Analysis of patentable distinction proceeds in two steps. First, as a matter of law, a court construes the disclaimed claim and the other claim and determines the differences. *See id.* Even if the claim language itself "does not adequately disclose the patentable bounds of the invention," a court "examines the specifications of both patents to ascertain any overlap in the claim scope for the [patentable distinction] analysis." *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1385 (Fed. Cir. 2003); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (specification is "'single best guide'" to claim meaning); *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1379 (Fed. Cir. 2012) (specification "considered only to the extent necessary to construe its claims," and not as prior art). Second, if there are differences between the claims, "the court determines whether the differences in subject matter between the two claims render the claims patentably distinct." *Eli Lilly*, 251 F.3d at 968. Claims that "do not add inventive matter" to the compared claim are patentably indistinct. *In re Webersinn*, 191 F.2d 403, 407 (CCPA 1951).

Under this standard, Claims 1-5 are anticipated by Claim 8, and Claims 9-10 are anticipated, or in the alternative obvious over, at least Claim 8. The lack of patentable distinction is clear from the intrinsic evidence, but Defendants also submit a declaration from Dr. John M. Lambert setting for the perspective of the POSA for the benefit of the Court. Exh. A.

[redacted]

1. Claims 1-5 are Anticipated by, and Thus Patentably Indistinct from, Claim 8

Claim 8 depends from Claims 1-5.[3] More specifically, the dependent Claim 8 is a species claim of Claims 1-5 "wherein the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of the antibody-drug conjugate." DX-0001 at Claim 8. The relationship of Claim 8 with respect to Claims 1-5 as well as the other disclaimed dependent Claims 9 and 10 is illustrated below:



As the Federal Circuit consistently recognizes in the context of anticipation, "a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." *Eli Lilly & Co.*, 251 F.3d at 971 (citing *In re Berg*, 140 F.3d at 1437 (Fed. Cir. 1998)); *Geneva Pharm.*, 349 F.3d at 1383. Because Claim 8 forms a species-genus relationship with Claims 1-5,

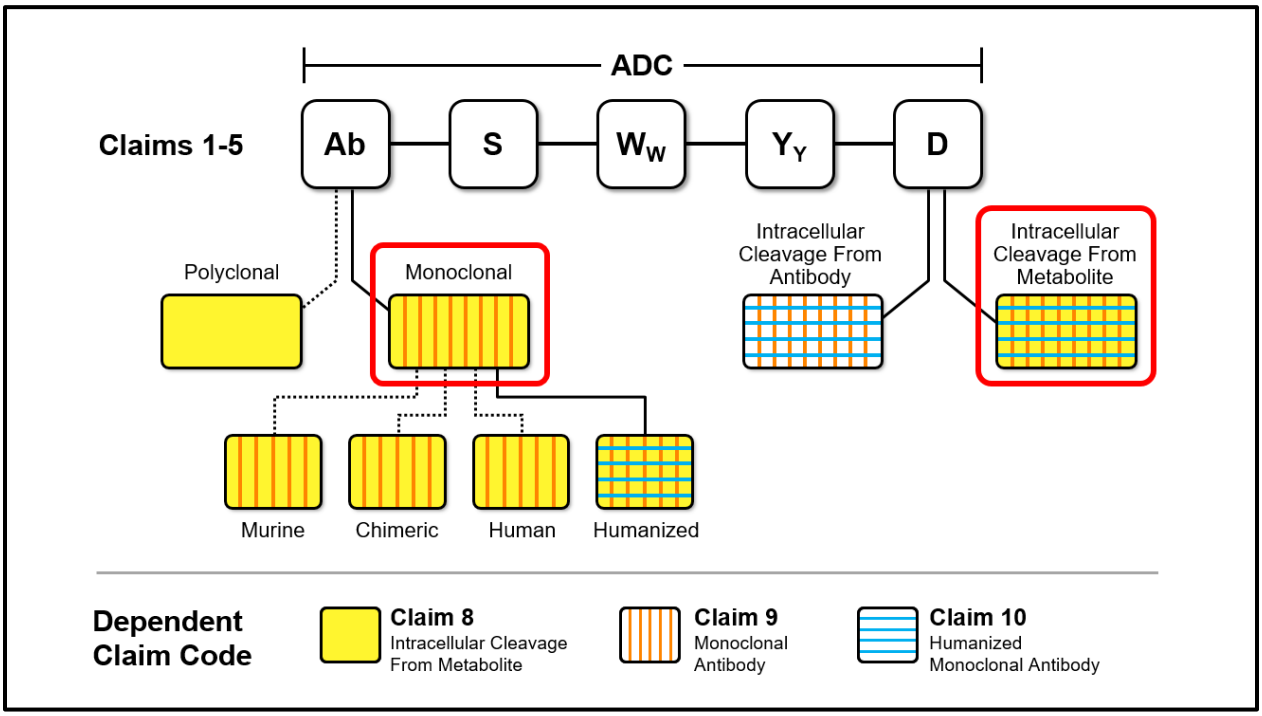
[3] Claim 8 is written as follows: "The antibody-drug conjugate compound of claim 1, 2, 3, 4, or 5, wherein the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of the antibody-drug conjugate."

[redacted]

Claim 8 thereby "anticipates" Claims 1-5, meaning Claims 1-5 are each patentably indistinct from Claim 8. *See* Exh. A ¶¶ 18-20.

2. Claim 9 Is Anticipated by, and Thus Patentably Indistinct from, Claim 8

Claims 9 is anticipated by, and patentably indistinct from, disclaimed Claim 8. Claim 9, which depends from Claims 1-5, provides that "the antibody [of Claims 1, 2, 3, 4, or 5] is a monoclonal antibody." As illustrated below, a comparison of Claims 8 and 9 shows no patentable distinction:



In the first step of the analysis, as noted above, Claim 8 is construed to determine any differences from Claim 9. *Eli Lilly*, 251 F.3d at 968. Claim 8, by its dependency from Claims 1-5, recites ADCs formed with an "antibody," without qualification or restriction. DX-0001 at Claims 1-5, 8. Thus, as a matter of plain claim language, the ADCs can be formed using any type of antibody, including monoclonal antibodies. Furthermore, a patentee may operate as his own lexicographer and define claim terms, *Phillips*, 415 F.3d at 1319, and here the specification of the

[redacted]

'039 patent expressly defines the term "antibody" to include monoclonal antibodies. DX-0001 at 22:21-41; Exh. A ¶ 15. Additionally, the specification teaches the use of monoclonal antibodies when making ADCs, and all of the specific antibody examples in the '039 patent are monoclonal antibodies. DX-0001 at 4:1-6:29. Moreover, the specification describes monoclonal antibodies as advantageous over polyclonal antibodies. DX-0001 at 22:42-55; Exh. A ¶ 23. Thus, the POSA would understand from the claim language in view of the specification that the invention defined in Claim 8 encompasses ADCs with monoclonal antibodies, exactly what is claimed in Claim 9. *See Geneva Pharm., Inc.*, 349 F.3d at 1385.

Further, the dependent claims confirm that "antibody" in independent Claims 1-5 includes monoclonal antibodies. "By definition, an independent claim is broader than a claim that depends from it, so if a dependent claim reads on a particular embodiment of the claimed invention, the corresponding independent claim must cover that embodiment as well." *Littelfuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1380 (Fed. Cir. 2002). This is confirmed by Claim 9's use of the term "wherein," which is "language for invoking an antecedent." *Univ. of Mass. v. L'Oréal S.A.*, 36 F.4th 1374, 1380 (Fed. Cir. 2022). Because Claim 9 recites the Claim 1-5 ADCs "wherein the antibody is a monoclonal antibody," independent Claims 1-5 cover ADCs with monoclonal antibodies. And because Claim 8 likewise depends from Claims 1-5, it too encompasses ADCs formed with monoclonal antibodies, "wherein the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of" the ADCs. Conversely, Claim 9, by its dependency from Claims 1-5, likewise includes monoclonal antibody ADCs with the same intracellular metabolite limitation. Claims 8 and 9 do not claim patentably distinct inventions.

Step two of the analysis is to "determine[] whether the differences in subject matter between the two claims render the claims patentably distinct." *Eli Lilly*, 251 F.3d at 968;

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MaxLinear, Inc., 880 F.3d at 1377 (claims are patentably indistinct if the differences between the claims "do not materially alter the question of invalidity"). Here, Claim 9 recites species (monoclonal-antibody ADCs "wherein the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of" the ADCs) of the broader Claim 8 genus (any ADC with the same intracellular-metabolite limitation). But that difference does not render the claims patentably distinct. A claimed genus can disclose (and anticipate) a species if it "describes to one skilled in this art not only the broad class but also this much more limited class within that broad class," even if the former "did not expressly spell out the limited class." *In re Petering*, 301 F.2d 676, 681 (CCPA 1962). The question is only whether "one skilled in the art would," upon reading the claimed genus (here, Claim 8), "at once envisage each member of this limited class." *Id.*; *Kennametal Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381-82 (Fed. Cir. 2015) (a person must be able to "immediately envisage" the claimed combination); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd*, 851 F.3d 1270, 1274 (Fed. Cir. 2017). The expressed preferences for certain types of compounds supports anticipation. *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 2009); *In re Petering*, 301 F.2d at 681.

Here, based on the intrinsic evidence alone, for the reasons given, the POSA would immediately envisage from the genus of claimed ADCs the more limited class of ADCs with monoclonal antibodies (one of the two major types of antibodies). The specification used not only monoclonal antibodies in the embodiments, but expressed a preference for monoclonal antibodies over polyclonal antibodies. DX-0001 at 4:1-6:29, 22:42-55; Exh. A ¶¶ 22-24. Additionally, even apart from the intrinsic evidence, the POSA at the time of the invention would understand immediately that a genus of ADCs formed with any "antibody" would include ADCs wherein the antibody was a monoclonal antibody. Indeed, the POSA would know that monoclonal antibodies

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were preferred because of their "numerous advantages over polyclonal antibodies, including their specificity in binding and the ability to reproducibly generate large quantities of identical antibodies (in contrast to more complex, larger, and non-uniform polyclonal antibodies)." Exh. A ¶¶ 22-24.

Alternatively, by defining "antibody" as used in Claims 1-5 and 8 to include both monoclonal and polyclonal antibodies, these Claims 8 and 9 necessarily overlap. Exh. A ¶ 26. The POSA would understand Claim 8 describes species of ADCs with monoclonal antibodies that are a part of the broader genus in Claim 9, which recites the ADCs of Claims 1-5 with monoclonal antibodies. Exh. A ¶ 26.

For all these reasons, Claim 8 anticipates Claim 9, and the two claims are not patentably distinct.

3. Claim 10 Is Anticipated by, and Thus Patentably Indistinct from, Claim 8

Claim 10, which depends from Claim 9, provides that "the antibody [of Claim 9] is a humanized monoclonal antibody." DX-0001 at Claim 10. As illustrated below, a similar analysis reveals that Claim 10 is anticipated by, and thus patentably indistinct from, Claim 8:

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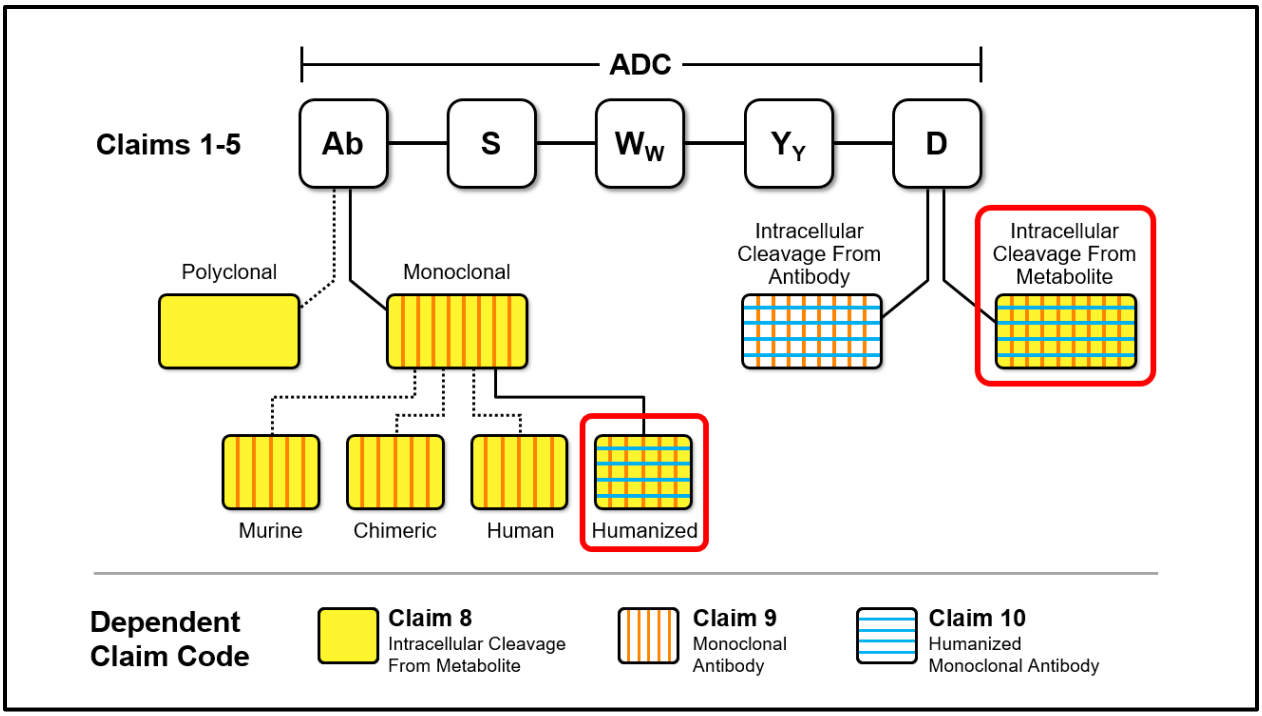

The first step is to construe and compare the two claims. As discussed above, the plain meaning of independent Claims 1-5, construed in light of the specification and the express definition, is that they recite the specified ADCs comprised of any antibody (including a monoclonal antibody) "wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate *or an intracellular metabolite of the antibody-drug conjugate*." DX-0001 at Claim 1 (emphasis added); *see also id.* at Claims 2-5. Accordingly, Claim 8, which depends from Claims 1-5, likewise comprises the recited ADCs with any antibody (including a humanized monoclonal antibody) but is restricted to intracellular cleavage from an intracellular metabolite. DX-0001 at Claim 8.

The POSA would understand from the specification that the broad and unqualified term "antibody" in Claims 1-5 and 8, which is expressly defined to include monoclonal antibodies, also encompasses humanized monoclonal antibodies. "The'039 patent specifically describes four types of monoclonal antibodies, including humanized monoclonal antibodies, as well as murine (derived

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from rodents), chimeric (a mix of rodent and human), and fully human monoclonal antibodies." Exh. A ¶ 16 (citing DX-0001 at 79:7-10, 84:44-47). The dependent claims confirm this construction. Claim 10, because it depends from Claim 9 (and thus from Claims 1-5), verifies that Claims 1-5 must be construed to encompass ADCs with humanized monoclonal antibodies. Claim 9 recites the ADCs of Claims 1-5 "*wherein* the antibody is a monoclonal antibody," and Claim 10 recites the ADCs of Claim 9 "*wherein* the antibody is a humanized monoclonal antibody," which verifies that the ADCs of independent claims 1-5 can have a humanized monoclonal antibody. *See Littelfuse, Inc.*, 29 F.4th at 1380; *L'Oréal S.A.*, 36 F.4th at 1380. And because the Claim 1-5 ADCs can be formed with humanized monoclonal antibodies, so too can Claim 8.

The differences between Claim 8 and 10, which stand in a genus-species relationship, do not render them patentably indistinct because the former anticipates the latter. Claim 8 recites all the Claim 1-5 ADCs wherein the drug moiety is intracellularly cleaved in a patient from an intracellular metabolite of the antibody-drug conjugate, *including* ADCs with humanized monoclonal antibodies. Claim 10, by its dependency from Claim 9 (and in turn Claims 1-5), encompasses ADCs with the same intracellular-cleavage limitation, but *restricted to* ADCs with humanized monoclonal antibodies.

There is no patentable distinction because the Claim 8 genus "describes to one skilled in this art not only the broad class but also this much more limited class" of Claim 10 "within that broad class" even if the smaller class is not described, for the POSA at the time of the invention would "at once envisage each member of this limited class." *In re Petering*, 301 F.2d at 681; *Kennametal Inc.*, 780 F.3d at 1381-82 (Fed. Cir. 2015) (a person must be able to "immediately envisage" the claimed combination). The POSA would know that monoclonal antibodies are the preferred antibody for ADCs, and it is well known that there are only four types of monoclonal

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antibodies. Exh. A ¶¶ 16, 22-24, 29. Moreover, as Dr. Lambert states, given that the claimed ADCs are for use "in a patient," DX-0001 at Claim 1,

> [B]ased on the art in 2004, the POSA would immediately envisage from Claim 8 using either a chimeric, a humanized, or a fully human monoclonal antibody when designing an ADC. While murine monoclonal antibodies (originating from rodent hosts) are mentioned in the '039 patent specification, they were known to have significant complications for use in ADCs, largely due to the induction of a HAMA response in patients. (DX 0001 at 23:35-43, 79:7-10, 84:44-47; DX-0083 at 2; DX-0085 at 4; DX-0086 at 5.) In fact, the '039 patent describes the risk of inducing a HAMA response, specifically noting that it can cause toxic shock or death. (DX-0001 at 23:35-43.)

Exh. A ¶ 30. Indeed, "[t]he '039 patent specifically provides trastuzumab as an example of an antibody used in ADCs and notes that '[b]ecause Trastuzumab is a humanized antibody, it minimizes any HAMA response in patients.'" Exh. A ¶ 29 (quoting DX-0001 at 5:23-24.) The POSA in 2004 would know that "the only ADCs that were being tested … were therefore ADCs using either chimeric or humanized monoclonal antibodies because they could be 'successfully administered to patients for a prolonged treatment duration without inducing a clinically meaningful immune response.'" *Id.* ¶ 31 (quoting Trail 2003 at 328, 333.) And the only FDA-approved ADC at the time used a humanized monoclonal antibody. *Id.* ¶ 32. Chimeric antibodies "did not fully eliminate the potential HAMA response and could still show significant immunogenicity in humans." *Id.* ¶ 31. Because it was known that human or humanized monoclonal antibodies were preferred for ADCs used to treat human patients, the POSA confronted with the invention defined in Claim 8 would immediately envisage the class of ADCs represented by Claim 10. *Id.* ¶¶ 28-29. Claim 8 anticipates Claim 10, and the two claims

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are not patentably distinct. *Id.* ¶ 33.[4]

Alternatively, by defining "antibody" as used in Claims 1-5 and 8 to include monoclonal antibodies, which include humanized monoclonal antibodies, these Claims 8 and 10 necessarily overlap. Exh. A ¶ 34. The POSA would understand Claim 8 describes species of ADCs with humanized monoclonal antibodies that are a part of the broader genus in Claim 10, which recites the ADCs of Claims 1-5 with humanized monoclonal antibodies. Exh. A ¶ 34.

4. Alternatively, Both Claims 9 and 10 Are Obvious Over Claim 8.

If there is no anticipation, "the question whether the two claimed compounds are 'patentably distinct' implicates the question of obviousness under § 103, which in the chemical context requires identifying some reason that would have led a chemist to modify the earlier compound to make the later compound with a reasonable expectation of success." *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012).

For similar reasons to those given above, the POSA would have been motivated based on the invention of Claim 8 to make ADCs using monoclonal antibodies, and would have reasonably expected ADCs using monoclonal antibodies to be more successful than ADCs using polyclonal antibodies. Exh. A ¶ 35. The specification describes monoclonal antibodies as advantageous over polyclonal antibodies (DX-0001 at 22:42-55), which the POSA would have understood at the time of the invention. As Dr. Lambert declares,

> In 1975, the development of monoclonal antibodies by Kohler and Milstein "revolutionized the field of immunology," and more specifically, launched "[t]he modern era of targeted therapy for cancer." (Ex. 2, Ross 2003 at 472; Ex. 3, Berger 2002 at 14; Ex. 4, Grossbard 1992 at 863; DX-0086 at 5; *see also* DX-

[4] Claims 1-5 recite ADCs with alternative cleavage functions. DX-0001 at Claims 1-5 (emphasis added). Thus, some species of Claims 9 and 10, which can have either cleavage function, are not in the Claim 8 genus, but that is irrelevant for anticipation purposes. If a claim is written in the alternative, it may be anticipated by a claim with either alternative function. *Brown v. 3M*, 265 F.3d 1349, 1352–53 (Fed. Cir. 2001).

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> 0079 at 1; DX-0083 at 1-2.) By 2004, monoclonal antibodies were known to have numerous advantages over polyclonal antibodies, including their specificity in binding and the ability to reproducibly generate large quantities of identical antibodies (in contrast to more complex, larger, and non-uniform polyclonal antibodies). (Ex. 5, Marsh 1988 at 213.) Given this, by the 2004 time period, the POSA would have known to make an ADC with a monoclonal antibody instead of a polyclonal antibody.

Exh. A ¶ 24. "Further, if we were to assume the POSA in 2004 would not have immediately envisaged from Claim 8 a class of ADCs using humanized monoclonal antibodies (*see, e.g.*, ¶¶ 27-34), another odd assumption given the limited choices and known preferences in the art, for essentially the same reasons the POSA would alternatively have found it obvious to modify the subject matter of Claim 8 to use humanized monoclonal antibodies." *Id.* ¶ 36.

Claim 10 is likewise obvious over Claim 8. Claim 10 recites the structure of Claim 8, in the alternative, but with the additional restriction that the antibody must be a humanized monoclonal antibody. The POSA at the time of the invention would have been motivated to make the ADCs of Claim 8 using a humanized monoclonal antibody. There are only four types of monoclonal antibodies; two of the four (murine and chimeric monoclonal antibodies) have the problems of HAMA response, which can cause toxic shock or death; and the only ADCs being tested involved human or humanized monoclonal antibodies. *Id.* ¶¶ 29-32. As Dr. Lambert reports:

> Humanized monoclonal antibodies were introduced to overcome this deficiency by further minimizing the risk of potential HAMA responses. (DX-0134 at 92, 97; DX-0086 at 5-6; Ex. 3, Berger 2002 at 17-18.) By 2004, "[n]umerous humanized antibodies [had] been designed and constructed, and many [were] being evaluated in clinical trials." (Ex. 3, Berger 2002 at 18.) In fact, at that time, the only FDA approved ADC (Mylotarg™) used a humanized monoclonal antibody (gemtuzumab).[5] (Ex. 7, Reichert 2001 at 822; DX-0083 at 3.)

[5] Mylotarg™ was later withdrawn from the U.S. Markets in 2010 for issues not related to the use of a humanized monoclonal antibody and reapproved in 2017. DX-0083 at 3, 14.

[redacted]

Exh. A ¶ 32. Thus, "[k]nowing and understanding the benefits of humanized monoclonal antibodies, the POSA designing an ADC within the scope of these claims would be motivated to use specifically a humanized monoclonal antibody, and would have a reasonable expectation of success as to that aspect of the ADC, given the well-known advantages of such antibodies, the industry's shift by 2004 to testing humanized monoclonal antibodies, and the fact that the only FDA-approved ADC at the time (Mylotarg™) used a humanized monoclonal antibody." Exh. A ¶ 36.

Because Claims 9 and 10 are obvious modifications of Claim 8, the claims are not patentably distinct.

D. Seagen Has No Remaining Cause of Action that is Supported by a Non-Defective Claim and the Case Must Be Dismissed

Even apart from patentable distinction, Seagen's disclaimer had the effect of disavowing the scope of the asserted claims. Claim 1, and all the asserted claims depending from it, recite ADCs with alternative cleavage limitations: "wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate *or* an intracellular metabolite of the antibody-drug conjugate." DX-0001 at Claim 1 (emphasis added). When Seagen disclaimed Claim 8, it surrendered to the public all ADCs with the latter limitation, and Seagen no longer has any property right in those ADCs. And by operation of law, that disclaimer "shall thereafter be considered as part of the original patent," *nunc pro tunc*. 35 U.S.C. § 253(a). As a result of the disclaimer, Seagen is deemed never to have had a property right in the ADCs of Claims 1-5 where the intracellular cleavage of the drug moiety is from an intracellular metabolite those ADCs. "Claims are not correctly construed to cover what was expressly disclaimed." *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000).

Even if defects in the remaining claims of the '039 patent could be cured by carving out

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their invalid claim scopes, the proper procedure for doing so is a reissue, which is governed by 35 U.S.C. § 251. This provision, which is titled "Reissue of defective patents," makes clear that it is the "Director," and only the "Director," who has the authority to reissue a patent that is "deemed wholly or partly inoperative or invalid":

> Whenever any patent is, through error, ***deemed wholly or partly inoperative or invalid***, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, ***the Director shall***, on the surrender of such patent and the payment of the fee required by law, ***reissue the patent*** for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent.

35 U.S.C. § 251 (a) (emphases added). "Director," in the context of Title 35, is the "Director of the United States Patent and Trademark Office." 35 U.S.C. § 3. In short, the PTO—and only the PTO—has the statutory authority to reissue a patent.

Reissue is not simply the proper procedure for correcting defective patents: It is ***the sole procedure*** for making such corrections. As the Supreme Court has long recognized, "[i]f a change [that alters the claim scope] could validly be made, it could only be under the provisions of the ***reissue*** statute, … which authorizes the alteration of the original invention in a reissued patent, upon surrender of the old patent, for its unexpired term." *Altoona Publix Theatres v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 491 (1935) (emphasis added).[6] And a patentee that surrenders a patent for reissue "extinguishes the patent. It is a legal cancellation of it, and hence can no more be the

[6] While the reissue statute has undergone two amendments since *Altoona*, neither changed the fundamental understanding that defective patents must be corrected at and by the PTO. *See*, *e.g.*, *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 26 (1997) (recognizing that "[t]he 1952 Patent Act is not materially different from the 1870 Act with regard to claiming, reissue, and the role of the PTO."); *see also* Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) (amending, among others, the 1952 Patent Act with the current language of § 251, all the while maintaining § 251 as the sole provision governing the reissue requirements).

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foundation for the assertion of a right after the surrender, than could an act of Congress which has been repealed."). *See Moffitt v. Garr*, 66 U.S. 273, 283 (1861).

The law does not permit Seagen to retain or recapture surrendered claims by suing others on unamended claims. As the Federal Circuit has said regarding surrenders of claim scope during prosecution:

> This court has noted that subject matter surrendered via claim amendments during prosecution is also relinquished for other claims containing the same limitation. *Builders Concrete, Inc. v. Bremerton Concrete Prods. Co.*, 757 F.2d 255, 260 (Fed. Cir. 1985). This court follows this rule to ensure consistent interpretation of the same claim terms in the same patent. In *Builders Concrete*, the patentee during prosecution surrendered claim scope by amending a claim that it later did not assert against the alleged infringer. Instead the patentee tried to recapture that same surrendered subject matter by asserting a claim that was not amended. This court estopped the patentee from interpreting the unamended claim to encompass the scope that was relinquished in the amended claim.

Glaxo Wellcome, Inc. v. Impax Labs., Inc., 356 F.3d 1348, 1356 (Fed. Cir. 2004). The same rule applies to surrender by disclaimer: the surrendered subject matter "is also relinquished for other claims containing the same limitation." *Id.*

Because the PTO is the sole authority to reissue a defective patent, and because a reissue is the proper and sole procedure available to correct the defects of the asserted claims (assuming that such corrections can even be made), this Court cannot amend the asserted claims of the '039 patent. Because by virtue of the disclaimer, Seagen has had no property right in the disclaimed invention from its inception, the claims are null and void. Accordingly, because there is no cause of action supported by a non-defective claim, this Court must vacate its judgment and dismiss the case in its entirety.

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VI. CONCLUSION

For the above reasons, Defendants respectfully request that this Court enter judgment in favor of Defendants on Claims 1-5, 9, 10 on the basis of disclaimer and cancellation, and declare Seagen's claims of infringement moot.

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Dated: August 15, 2022

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who have consented to electronic service are being served with a copy of this document via electronic mail on August 15, 2022.

/s/ Preston K. Ratliff II

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